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APPLICATION NO.	LICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,878 07/14/2003		Ole Skyggebjerg	6531.200-US	6821	
23650	7590 12/01/2005			EXAMINER	
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100 COLLE			ART UNIT	PAPER NUMBER	
PRINCETO	N, NJ 08	3540	2854		

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will exply SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 14 July 2003. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-14 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. Claim(s) is/are allowed. Claim(s) is/are allowed. Claim(s) is/are allowed. Claim(s) are subject to restriction and/or election requirement.		Application No.	Applicant(s)					
Leo T. Hinze	Office Action Samuel		SKYGGEBJERG ET AL.					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.135(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply septiled above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than these months after the mailing date of this communication, even if timely filed, may reduce any seamed patient term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 14 July 2003. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-14 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) see Continuation Sheet is/are rejected. 7) Claim(s) 3-9 and 11/7-11/9, 12/11/7-12/11/9, 13/12/11/7-13/12/11/9 and 14/7-14/9 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner.	Oπice Action Summary	Examiner	Art Unit					
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Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority under 35 U.S.C. § 119	Priority under 35 U.S.C. § 119							
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).								
a) ⊠ All b) □ Some * c) □ None of:	-(d) 01 (i).							
1.⊠ Certified copies of the priority documents have been received.								
2. Certified copies of the priority documents have been received in Application No								
3. Copies of the certified copies of the priority documents have been received in this National Stage								
application from the International Bureau (PCT Rule 17.2(a)).								
* See the attached detailed Office action for a list of the certified copies not received.								
attachment(s)								
) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date								
) 🔯 Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) 5) 🛄 Notice of Informal Patent Application (PTO-152)								
Paper No(s)/Mail Date <u>20031020</u> . 6) Other:	Paper No(s)/Mail Date <u>20031020</u> .	6)						

Continuation of Disposition of Claims: Claims rejected are 1-6, 10, 11/1-11/6,12/11/1-12/11/6, 13/12/11/1-13/12/11/6, 14/1-14/6, 11/10, 12/11/10, 13/12/11/10 and 14/10.

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DETAILED ACTION

Claim Objections

Claims 7, 8, 9, 10, 11/7-10, 12/11/7-10, 13/12/11/7-10 and 14/7-10 are objected to because of 1.

the following informalities:

Line 4 of claims 7, 8 and 9 and line 3 of claim 10 contain the limitation "the third time stamp."

This term lacks a proper antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis

for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on

sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, 10, 11/1, 11/3, 11/6 and 11/10 are rejected under 35 U.S.C. 102(b) as being 3.

anticipated by Hamilton et al., US 4,939,705 (Hamilton).

Regarding claim 1, Hamilton teaches a timer device, comprising: contact means (21, Fig. 2) a.

operatable between a first condition and a second condition, timer means (32 kHz clock frequency, col.

3, 1. 58; Fig. 3), means for storing (RAM 42, Fig. 3) a first time stamp, a second time stamp, and a first

time-period value, control means (microprocessor 32, Fig. 3) adapted for: setting a first time stamp in

response to the contact means being operated between the first condition and the second condition

("cap off" signal, col. 4, 1. 9), setting a second time stamp in response to the contact means being operated between the second condition and the first condition ("cap is replaced," col. 4, 1, 10), calculating the time elapsed between the first and second time stamps, comparing the elapsed time with the first time-period value, and performing a first control action if the elapsed time is greater than the first time-period value ("time interval between opening and reclosing the top of the drug container... measured and compared to a predetermined standard," col. 4, 11. 34-36).

- b. Regarding claim 3, Hamilton also teaches means for storing (RAM 42, Fig. 3) a third time stamp, wherein the first control action replaces the third time stamp with the first or second time stamp or a time value calculated on the basis of the first and/or second time stamp. Device stores time dose was taken as a third time stamp, and subsequently stores the time the last dose was taken, which is the first or second time stamp, i.e. the time the cap was removed/replaced for a subsequent dose (col. 4, ll. 63-65).
- c. Regarding claim 6, Hamilton also teaches means for storing (RAM 42, Fig. 3) a second time-period value, and wherein the control means is further adapted for: comparing the elapsed time with the second time-period value, and performing a second control action if the elapsed time is greater than the second time-period value. The second time interval is that interval which, when compared to the time the cap was open, would result in "too long an interval" (col. 4, Il. 50-52). The second control action would be indication that possibly multiple doses were taken (col. 4, I. 52), or an indication that a dose was taken and the container not closed until the subsequent dose was taken (col. 4, Il. 60-63).
- d. Regarding claim 10, Hamilton also teaches display means (13, Fig. 1) for displaying one or more time stamps and/or for indicating the time lapsed since the third time stamp.

e. Regarding claims 11/1, 11/3, 11/6 and 11/10, Hamilton also teaches a device for use by a patient for medical self treatment, comprising: a first device portion (11, Fig. 1) for performing an operation, a second device portion (12, Fig. 1) comprising a timer device as defined in any of the previous claims (see rejections of claims 1, 3, 6 and 10 above), wherein the first and second device portions have mutually cooperating coupling means for detachably assembling the first and second device portions to form a single portable unit, the contact means being operated between the first condition and the second condition when the first and second device portions are detached from each other, and the contact means being operated between the second condition and the first condition when the first and second device portions are attached to each other (col. 3, ll. 44-47).

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in

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order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 2 and 11/2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton in view of Hildebrandt, US 6,845,064 (Hildebrandt).

a. Regarding claim 2:

Hamilton teaches all that is claimed as discussed in claim 1 above, including a display means (13, Fig. 1) capable of indicating the time lapsed since reset of a stop watch means.

Hamilton does not teach stop watch means adapted for being reset in response to the control action, and display means (33) for indicating the time lapsed since reset of the stop watch means.

Hildebrandt teaches an add-on medicine dispenser timer, including stop watch means adapted for being reset in response to the control action ("a simple chronometer that indicates the length of time which has lapsed since when the cap was replaced on the medicine vial after removal for a dosage," col. 4, Il. 22-25). Such a mechanism is advantageous for providing for the timely administration of medication (col., Il. 15-16) that prevents overdosing or underdosing (col. 1, Il. 18-19).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hamilton to include stop watch means adapted for being reset in response to the control action, because Hildebrandt teaches that such a mechanism is advantageous for providing for the timely administration of medication that prevents overdosing or underdosing.

b. Regarding claim 11/2, the combination of Hamilton and Hildebrandt teaches all that is claimed as discussed above. Hamilton also teaches a device for use by a patient for medical self treatment,

comprising: a first device portion (11, Fig. 1) for performing an operation, a second device portion (12, Fig. 1) comprising a timer device as defined in any of the previous claims (see rejections of claims 1, 3, 6 and 10 above), wherein the first and second device portions have mutually cooperating coupling means for detachably assembling the first and second device portions to form a single portable unit, the contact means being operated between the first condition and the second condition when the first and second device portions are detached from each other, and the contact means being operated between the second condition and the first condition when the first and second device portions are attached to each other (col. 3, 11, 44-47).

- 6. Claims 4, 5, 11/4 and 11/5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton in view of de la Huerga, US 6,529,446 (de la Huerga).
- a. Regarding claim 4:

Hamilton teaches all that is claimed as discussed in the rejection of claim 1 above, including automatically performing a first control action ("correct drug dispensing events... stored into a readable memory," col. 4, ll. 63-66).

Hamilton does not teach first actuation means for canceling the first control action.

It has been held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art. See MPEP § 2144.04 (III).

De la Huerga teaches an interactive medication container that includes buttons for canceling automatic alarms (col. 10, 1. 67 through col. 11, 1. 6; col. 42, ll. 38-45). Such a device provides improved patient compliance in taking the appropriate medication on schedule.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hamilton to include buttons to allow a patient to control or override the setting of alarms and the indication of whether a dose was administered as taught by de la Huerga, because a person having ordinary skill in the art would recognize that such manual controls of an automatic activity may improve patient compliance in taking the appropriate medication on schedule by allowing the patient to modify the dosage schedule as necessary in ways that would not be possible with a fully automatic system which may not be able to compensate for unusual real-world conditions.

b. Regarding claim 5:

Hamilton teaches all that is claimed as discussed in the rejection of claim 1 above, including automatically performing a first control action ("correct drug dispensing events... stored into a readable memory," col. 4, ll. 63-66).

Hamilton does not teach first actuation means for confirming the first control action, whereby no confirmation will cancel the first control action.

It has been held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art. See MPEP § 2144.04 (III).

De la Huerga teaches an interactive medication container that includes buttons for canceling automatic alarms (col. 10, l. 67 through col. 11, l. 6; col. 42, ll. 38-45). Such a device provides improved patient compliance in taking the appropriate medication on schedule.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hamilton to include buttons to allow a patient to control or override the setting of

alarms and the indication of whether a dose was administered as taught by de la Huerga, because a person having ordinary skill in the art would recognize that such manual controls of an automatic activity may improve patient compliance in taking the appropriate medication on schedule by allowing the patient to modify the dosage schedule as necessary in ways that would not be possible with a fully automatic system which may not be able to compensate for unusual real-world conditions.

- c. Regarding claims 11/4 and 11/5, the combination of Hamilton and de la Huerga teaches all that is claimed as discussed in the rejection of claims 4 and 5 above. Hamilton also teaches a device for use by a patient for medical self treatment, comprising: a first device portion (11, Fig. 1) for performing an operation, a second device portion (12, Fig. 1) comprising a timer device as defined in any of the previous claims (see rejections of claims 1, 3, 6 and 10 above), wherein the first and second device portions have mutually cooperating coupling means for detachably assembling the first and second device portions to form a single portable unit, the contact means being operated between the first condition and the second condition when the first and second device portions are detached from each other, and the contact means being operated between the second condition and the first condition when the first and second device portions are attached to each other (col. 3, II. 44-47).
- 7. Claims 12/11/1, 12/11/3, 12/11/6, 12/11/10, 13/12/11/1, 13/12/11/3, 13/12/11/6, 13/12/11/10, 14/1, 14/3, 14/6 and 14/10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton in view Lav et al, US 6,302,855 (Lav).
- a. Regarding claims 12/11/1, 12/11/3, 12/11/6 and 12/11/10:

Hamilton teaches all that is claimed as discussed in the rejection of claims 11/1, 11/3, 11/6 and 11/10 above, including wherein the first device portion comprises means for administering a preset

dose of a drug to the patient, wherein the means comprises a pill bottle that allows a patient to select a single preset dose in the form of a pill.

Hamilton does not teach wherein the means for administering a preset dose of a drug to the patient is a syringe.

Lav teaches a multi-piece device for administering a single preset dose in the form of an injection from a syringe, including a second device portion in the form of a cap (10, Fig. 1) and a first device portion (20, Fig. 2) in the form of a syringe and holder.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to combine the drug dispensing event detector of Hamilton with the drug dispensing mechanism of Lav, because a person having ordinary skill in the art would recognize that there are many ways for a patient to receive a single preset dose of a medication, including orally ingested pills, liquids and injections, and that regardless of the method of delivering the dose, it is critical that the dose is properly administered to a patient, and combining Hamilton and Lav would provide a mechanism to ensure that single preset doses administered by syringe are properly administered, thereby preventing dangerous over or under-dosing.

b. Regarding claims 13/12/11/1, 13/12/11/3, 13/12/11/6 and 13/12/11/10, the combination of Hamilton and Lav teaches all that is claimed as discussed in the rejection of claims 12/11/1, 12/11/3, 12/11/6 and 12/11/10 above. As combined with Hamilton above, Lav also teaches wherein the first device portion further comprises a distal end portion at which an infusion needle is or can be mounted (20, Fig. 2), and the second device portion is in the form of a cap (10, Fig. 2) adapted to cover the

distal end portion when the first and second device portions are attached to each other, the cap preferably comprising a body fluid analyzer (34, Fig. 2).

Regarding claims 14/1, 14/3, 14/6 and 14/10: c.

Hamilton teaches all that is claimed as discussed in the rejection of claims 1, 3, 6 and 10 above, including a cap (12, Fig. 1) having an open end and an interior space adapted to receive a medical device (11, Fig. 2), the medical device comprising means for administering a preset dose of a drug to the patient (patient can select one preset dose from the bottle), the cap comprising a timer device as defined in any of claims 1-10, wherein the contact means can be operated between the first condition and the second condition when the cap and the medical device are removed from each other (col. 4, 11. 8-21), and the contact means can be operated between the second condition and the first condition when the medical device are received in the cap interior (col. 4, ll. 8-21).

Hamilton does not teach wherein the means for administering a preset dose of a drug to the patient is a syringe.

Lav teaches a multi-piece device for administering a single preset dose in the form of an injection from a syringe, including a second device portion in the form of a cap (10, Fig. 1) and a first device portion (20, Fig. 2) in the form of a syringe and holder.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to combine the drug dispensing event detector of Hamilton with the drug dispensing mechanism of Lav, because a person having ordinary skill in the art would recognize that there are many ways for a patient to receive a single preset dose of a medication, including orally ingested pills, liquids and injections, and that regardless of the method of delivering the dose, it is critical that the

dose is properly administered to a patient, and combining Hamilton and Lav would provide a mechanism to ensure that single preset doses administered by syringe are properly administered, thereby preventing dangerous over or under-dosing.

8. Claims 12/11/2, 13/12/11/2 and 14/2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton in view of Hildebrandt, and further in view of Lav.

a. Regarding claim 12/11/2:

The combination of Hamilton and Hildebrandt teaches all that is claimed as discussed in the rejection of claim 11/2 above, including wherein the first device portion comprises means for administering a preset dose of a drug to the patient, wherein the means comprises a pill bottle (Hamilton, 11, Fig. 1) that allows a patient to select a single preset dose in the form of a pill.

The combination of Hamilton and Hildebrandt does not teach wherein the means for administering a preset dose of a drug to the patient is a syringe.

Lav teaches a multi-piece device for administering a single preset dose in the form of an injection from a syringe, including a second device portion in the form of a cap (10, Fig. 1) and a first device portion (20, Fig. 2) in the form of a syringe and holder.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to combine the drug dispensing event detector of Hamilton with the drug dispensing mechanism of Lav, because a person having ordinary skill in the art would recognize that there are many ways for a patient to receive a single preset dose of a medication, including orally ingested pills, liquids and injections, and that regardless of the method of delivering the dose, it is critical that the dose is properly administered to a patient, and combining Hamilton and Lav would provide a

mechanism to ensure that single preset doses administered by syringe are properly administered, thereby preventing dangerous over or under-dosing.

Regarding claim 13/12/11/2, the combination of Hamilton, Hildebrandt and Lav teaches all that b. is claimed as discussed in the rejection of claim 12/11/2 above. As combined with Hamilton and Hildebrandt above, Lav also teaches wherein the first device portion further comprises a distal end portion at which an infusion needle is or can be mounted (20, Fig. 2), and the second device portion is in the form of a cap (10, Fig. 2) adapted to cover the distal end portion when the first and second device portions are attached to each other, the cap preferably comprising a body fluid analyzer (34, Fig. 2).

Regarding claim 14/2: C.

The combination of Hamilton and Hildebrandt teaches all that is claimed as discussed in the rejection of claims 1, 3, 6 and 10 above, including a cap (Hamilton, 12, Fig. 1) having an open end and an interior space adapted to receive a medical device (Hamilton, 11, Fig. 2), the medical device comprising means for administering a preset dose of a drug to the patient (patient can select one preset dose from the bottle), the cap comprising a timer device as defined in any of claims 1-10, wherein the contact means can be operated between the first condition and the second condition when the cap and the medical device are removed from each other (Hamilton, col. 4, ll. 8-21), and the contact means can be operated between the second condition and the first condition when the medical device are received in the cap interior (Hamilton, col. 4, ll. 8-21).

The combination of Hamilton and Hildebrandt does not teach wherein the means for administering a preset dose of a drug to the patient is a syringe.

Lav teaches a multi-piece device for administering a single preset dose in the form of an injection from a syringe, including a second device portion in the form of a cap (10, Fig. 1) and a first device portion (20, Fig. 2) in the form of a syringe and holder.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to combine the drug dispensing event detector of Hamilton with the drug dispensing mechanism of Lav, because a person having ordinary skill in the art would recognize that there are many ways for a patient to receive a single preset dose of a medication, including orally ingested pills, liquids and injections, and that regardless of the method of delivering the dose, it is critical that the dose is properly administered to a patient, and combining Hamilton and Lav would provide a mechanism to ensure that single preset doses administered by syringe are properly administered, thereby preventing dangerous over or under-dosing.

- Claims 12/11/4, 12/11/5, 13/12/11/4, 13/12/11/4, 14/4 and 14/5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton in view of de la Huerga, and further in view of Lav.
- Regarding claims 12/11/4 and 12/11/5: a.

The combination of Hamilton and de la Huerga teaches all that is claimed as discussed in the rejection of claims 11/4 and 11/5 above, including wherein the first device portion comprises means for administering a preset dose of a drug to the patient, wherein the means comprises a pill bottle (Hamilton, 11, Fig. 1) that allows a patient to select a single preset dose in the form of a pill.

The combination of Hamilton and de la Huerga does not teach wherein the means for administering a preset dose of a drug to the patient is a syringe.

Lav teaches a multi-piece device for administering a single preset dose in the form of an injection from a syringe, including a second device portion in the form of a cap (10, Fig. 1) and a first device portion (20, Fig. 2) in the form of a syringe and holder.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to combine the drug dispensing event detector of Hamilton with the drug dispensing mechanism of Lav, because a person having ordinary skill in the art would recognize that there are many ways for a patient to receive a single preset dose of a medication, including orally ingested pills, liquids and injections, and that regardless of the method of delivering the dose, it is critical that the dose is properly administered to a patient, and combining Hamilton and Lav would provide a mechanism to ensure that single preset doses administered by syringe are properly administered, thereby preventing dangerous over or under-dosing.

- Regarding claims 13/12/11/4 and 13/12/11/5, the combination of Hamilton, de la Huerga and b. Lav teaches all that is claimed as discussed in the rejection of claims 12/11/4 and 12/11/5 above. As combined with Hamilton and de la Huerga above, Lav also teaches wherein the first device portion further comprises a distal end portion at which an infusion needle is or can be mounted (20, Fig. 2), and the second device portion is in the form of a cap (10, Fig. 2) adapted to cover the distal end portion when the first and second device portions are attached to each other, the cap preferably comprising a body fluid analyzer (34, Fig. 2).
- Regarding claims 14/4 and 14/5: C.

The combination of Hamilton and de la Huerga teaches all that is claimed as discussed in the rejection of claims 4 and 5 above, including a cap (Hamilton, 12, Fig. 1) having an open end and an

interior space adapted to receive a medical device (Hamilton, 11, Fig. 2), the medical device comprising means for administering a preset dose of a drug to the patient (patient can select one preset dose from the bottle), the cap comprising a timer device as defined in any of claims 1-10, wherein the contact means can be operated between the first condition and the second condition when the cap and the medical device are removed from each other (Hamilton, col. 4, II. 8-21), and the contact means can be operated between the second condition and the first condition when the medical device are received in the cap interior (Hamilton, col. 4, II. 8-21).

The combination of Hamilton and de la Huerga does not teach wherein the means for administering a preset dose of a drug to the patient is a syringe.

Lav teaches a multi-piece device for administering a single preset dose in the form of an injection from a syringe, including a second device portion in the form of a cap (10, Fig. 1) and a first device portion (20, Fig. 2) in the form of a syringe and holder.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to combine the drug dispensing event detector of Hamilton with the drug dispensing mechanism of Lav, because a person having ordinary skill in the art would recognize that there are many ways for a patient to receive a single preset dose of a medication, including orally ingested pills, liquids and injections, and that regardless of the method of delivering the dose, it is critical that the dose is properly administered to a patient, and combining Hamilton and Lav would provide a mechanism to ensure that single preset doses administered by syringe are properly administered, thereby preventing dangerous over or under-dosing.

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Allowable Subject Matter

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10. Claims 7-9, 11/7-9, 12/11/7-9, 13/12/11/7-9 and 14/7-9 are objected to as being dependent

upon a rejected base claim, but would be allowable if rewritten in independent form including all of the

limitations of the base claim and any intervening claims and to overcome the other claim objections

described above.

11. The following is a statement of reasons for the indication of allowable subject matter:

a. Regarding claims 7 and 8, the prior art of record does not teach or render obvious a timer

device having all of the structure and functionality as claimed, including second actuation means,

wherein the second control action replaces the third time stamp with the second time stamp or, in

response to actuation of the second actuation means, with the first time stamp.

b. Regarding claim 9, the prior art of record does not teach or render obvious a timer device

having all of the structure and functionality as claimed, including second actuation means, wherein the

second control action replaces the third time stamp with the first time stamp or, in response to

actuation of the second actuation means, with the second time stamp.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's

disclosure.

Any inquiry concerning this communication or earlier communications from the examiner

should be directed to Leo T. Hinze whose telephone number is (571) 272-2167. The examiner can

normally be reached on M-F 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Hirshfeld can be reached on (571) 272-2168. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leo T. Hinze Patent Examiner AU 2854 25 November 2005

ANDREW H. HIRSHFELD SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 2800